

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE

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*In Re: Valsartan, Losartan, and Irbesartan* ) **19-MD-2875 (RBK-SAK)**  
Products Liability Litigation )  
   ) **Opinion and Order RE:**  
   ) **Parties' Objections to Special Master Report**  
   ) **and accompanying Special Master Order 46**  
   )  
*This document applies to all cases.*         )  
   )  
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**KUGLER, District Judge:**

**THIS MATTER HAVING COME BEFORE** the Court, pursuant to Fed. R. Civ. P. ["FRCP"] 53(f), upon four separate Motions to Adopt in Part and Object in Part to the Special Master's Report ["Report"] (Doc. No. 1614) and to the accompanying Special Master Order 46 ["SMO 46"] (Doc. No. 1615);

**THESE FOUR MOTIONS RELATING TO** plaintiffs' Motion for Leave to Amend the Master Complaints ["Motion to Amend" or "MTA"] (Doc. No. 1148);

**THE COURT FINDING** these motions to concern : 1) legal standing of the named plaintiffs to raise out-of-state claims; 2) the negligence claims against the Wholesaler Defendants ["Wholesalers"] and the Pharmacy Defendants ["Pharmacies"], and 3) breach of implied warranty claims raised against the Pharmacies;

**THE COURT HAVING CONSIDERED** the submissions of the parties without a hearing (in accordance with Local Rule 78.1(b)), and for the reasons stated below, and for good cause shown:

- 1) As to the Standing of Named Plaintiffs in the Proposed Economic Loss Master Complaint and the Proposed Medical Monitoring Complaint, the Court **GRANTS** plaintiffs' motion (Doc. No. 1694) and **DENIES** Manufacturer Defendants' ["MFRs"] Motion (Doc. No. 1690), Pharmacies' Motion (Doc. No. 1692), and Wholesalers' Motion (Doc. No. 1695), and **AFFIRMS** the Report at Doc. No. 1614: 10-12 and SMO 46 at Doc. No. 1615: ¶12);
- 2) As to the Negligence Claims against the Wholesalers and the Pharmacies, the Court **DENIES** plaintiffs' motion (Doc. No. 1694) and **AFFIRMS** the Report at Doc. No. 1614: 34-37 and SMO 46 at Doc. No. 1615: ¶9; and
- 3) As to the Breach of Implied Warranty Claims against the Pharmacies, the Court **REVISES** the ruling of the Report and SMO 46 at Doc. No. 1615: ¶6 and **GRANTS** plaintiffs' motion to assert breach of implied warranty claims under the laws of: Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Indiana, Maryland, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Wisconsin, and Wyoming.
- 4) The Court **ORDERS** no party may bring future motions or objections regarding plaintiffs' Motions to Amend the breach of implied warranty claims in the Master Complaints.
- 5) The Court **AFFIRMS** in all other respects the Report (Doc. No. 1614) and SMO46, particularly, at Doc. No. 1615: paragraphs 1-5, 7-11.

Table 1 below itemizes the parties' submissions regarding their objections to the Report, which reduce to these issues: 1) objections by all three defendant groups to the Report's ruling on standing of named plaintiffs to represent claims in states where they do not reside; 2) the Pharmacies' and the Wholesalers' requests to adopt certain Report rulings on

specific causes of action; and 3) plaintiffs' objections to the Report rulings denying negligence claims against the Wholesalers and the Pharmacies; and 4) breach of implied warranty claims against the Pharmacies.

**Table 1. Parties' Objections**

Motion	Movant / Doc. No.	Opposition / Doc. No.	Reply / Doc. No.
<b>1: Mfrs on Standing</b>  <b>Objection to Report Ruling on Standing</b> , viz., that unnamed class action plaintiffs had standing to raise out-of-state claims in the three Master Complaints	<b>Manufacturer defendants</b> ["Mfrs"] / Doc. No. 1690-1 (Brief)	Plaintiffs ["Ps"] / Doc. No. 1781	Mfrs/ Doc. No. 1800
<b>2: Pharmacies on Specific Causes of Action</b>  <b>Request Adoption</b> of Report Rulings on specific claims and seeking dismissal of these with prejudice in the Master Complaints  <b>And Objection to Report Ruling on Standing</b>	<b>Pharmacy Defendants</b> ["Pharmacies"] / Doc. No. 1692-1 (Brief)	Plaintiffs / Doc. No. 1782	Pharmacies/ Doc. No. 1801
<b>3: Wholesalers Specific Causes of Action</b>  <b>Request Adoption</b> of Order as to Wholesalers re Express warranty claims, implied warranty claims, fraud, and a medical monitoring claim in relevant Master Complaints  <b>And Objection to Report Ruling on Standing</b>	<b>Wholesaler Defendants</b> ["Wholesalers"] / Doc. No. 1695-1 (Brief)	Plaintiffs/ Doc. No. 1783	Wholesalers/ Doc. No. 1802
<b>4: Plaintiffs Negligence and Implied Warranty Claims</b>  <b>Object to Report Rulings</b> denying	Plaintiffs / Doc. No. 1694	Wholesalers / Doc. No. 1773  Pharmacies /	Plaintiffs/ Doc. No. 1803

Negligence claims against Wholesalers & Pharmacies, and Implied Warranty claims against Pharmacies		Doc. No. 1780	
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### **1.0     Facts and Background:**

As the parties are more than familiar with the facts and background, these are kept to a minimum. In 2019, plaintiffs filed three Master Complaints against the three groups of defendants: Manufacturers (Mfrs), Wholesalers, and Pharmacies. The complaints were styled as Personal Injury Master Complaint ["PIMC"], Medical Monitoring Master Complaint [MMMC] and the Economic Loss Master Complaint [ELMC].

About July 2019, defendants filed Motions to Dismiss ["MTDs"] various claims in each Master Complaint. From December 2020 to 12 March 2021, the Court issued six opinions regarding the MTDs. Of note here, MTD Opinion 2 (Doc. No. 728: 18- 19) ruled, among other things, that named class action plaintiffs do not have standing to assert claims under the laws of states where they do not reside and were not injured; MTD Opinion 3 (Doc. No. 775) resolved the MTDs for breach of warranty claims; and, MTD Opinion 6 (Doc. No. 1020) resolved negligence claims.

In April 2021, Plaintiffs filed a motion to amend ["MTA"] (Doc. No. 1148) the Master Complaints in accordance with the rulings in the six MTD Opinions, and submitted Proposed amended Master Complaints. These are denoted herein respectively as PPIMC (proposed Personal Injury Master Complaint), PMMMC, and PELMC. After full briefing on the Motion to Amend, on 7 October 2021, the Discovery Special Master issued to the Court a report and recommendations ["the Report"] (Doc. No. 1614) and an order ["the Order" or "SMO 46"] (Doc.

No. 1615) regarding plaintiffs' motion to amend and gave a deadline of 29 October 2021 by which to object.

On 29 October 2021, the parties filed four objections to the Report and Order: Doc. No. 1690 with accompanying brief at Doc. No. 1690-1, by the Mfrs; Doc. No. 1692 with accompanying brief at Doc. No. 1692-1, by the Pharmacies; Doc. No. 1695 with accompanying brief at Doc. No. 1695-1, by the Wholesalers; and Doc. No. 1694, by plaintiffs.

This Opinion/Order resolves these objections.

## **2.0    LEGAL STANDARD: Under *Fed. R. Civ. P. 53 (f)***

Under the FRCP, the court "may adopt or affirm; modify; wholly or partly reject or reverse; or resubmit ... with instructions" a Special Master's report and recommendations. *Rule 53(f)(1)*. Review of the Special Master's conclusions of law is *de novo*. *Rule 53(f)(4)*<sup>1</sup>. Where, as here, the parties have not stipulated otherwise, the court also reviews the Special Master's findings of fact *de novo*. *Rule 53(f)(3)*.

## **3.0    DISCUSSION**

### **3.1    Out-of-State Standing of Named Plaintiffs as Decided in SMO 46**

The SMO 46 (Doc. No. 1615:¶12) and the Report (Doc. No. 1614: 10-12) reversed this Court's ruling in MTD Opinion 2 (Doc. No. 728: 18-19), which had been that named, class

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<sup>1</sup> FRCP 5(f) states:

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(3) *Reviewing Factual Findings*. The court must decide *de novo* all objections to findings of fact made or recommended by a master, unless the parties, with the court's approval, stipulate that:

(A) the findings will be reviewed for clear error; or

(B) the findings of a master appointed under Rule 53(a)(1)(A) or (C) will be final.

(4) *Reviewing Legal Conclusions*. The court must decide *de novo* all objections to conclusions of law made or recommended by a master.

action representative have no standing to assert claims in the PELMC and the PMMMC in any jurisdiction where they do not reside and were injured. In MTD Opinion 2 (Doc. No. 728:18-19), this Court narrowed the issue to whether **named** (as opposed to unnamed, putative) class representatives had standing to represent those putative plaintiffs residing in states other than where the named representatives resided. In concluding **named** class representatives had no such standing, the MTD Opinion 2 followed a District of New Jersey case, *Ponizio v. Mercedes-Benz USA, LLC*, 447 F.Supp.3d 194, (D.N.J. 2020). *Ponizio*, in turn, had relied on an “impression” gleaned from Supreme Court cases that standing requirements are not satisfied in jurisdictions where a named plaintiff is not a resident. Put simply, in MTD Opinion 2, this Court ruled that, if there is no named plaintiff residing in each jurisdiction where the injury occurred, then there is no standing to bring claims in that jurisdiction.

Upon a *de novo* review, however, the Court finds this ruling was not fully considered and has revised it for the reasons below. Consequently, the Court affirms SMO 46 and the Report as to the standing issue.

The Mfrs, Wholesalers, and Pharmacies are united in their contentions that MTD Opinion 2 correctly grounded its conclusion on *Ponizio*. However, after review of the two Supreme Court cases on which *Ponizio* relied --*DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 337, 126 S.Ct. 1854, 164 L.Ed.2d 589 (2006) and *O'Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed.2d 674 (1974)—we find these inapposite to the standing issue raised here.

In *Daimler*, the question was whether taxpayers of Ohio state tax had standing to challenge the tax credits Ohio gave to Daimler car manufacturing plants. Taxpayers of Ohio state tax argued the Daimler tax credits depleted the state treasury, thereby increasing their

relative tax burden. The issue in *Daimler* was that the taxpayers could not demonstrate the standing requirement of a concrete, particularized injury; it was not the standing requirement of traceability of injury to those taxpayers. *Daimler*, 547 U.S. at 342-345.<sup>2</sup> Since traceability is the precise issue here, any “impression” gleaned from *Daimler* is inapposite. To the point, in *Daimler*, there could have been no traceability question because each plaintiff, even if unnamed or non-resident, paid Ohio state tax and therefore belonged to a class with a clearly defined and traceable boundary. The *Ponzi* Court’s reliance on *Daimler* seems misplaced as *Daimler* had nothing to do with whether the plaintiffs were putative, unnamed, or named. Likewise, the *Ponzi* Court’s citation to *O’Shea* is neither illuminating nor useful in resolving this dispute. *O’Shea* concerned whether plaintiffs had a ‘personal stake in the outcome’, that is, whether their injury was not abstract but concrete and particularized. *O’Shea*, 414 U.S. at 493-494. Again, that issue is not relevant to the traceability question here. And, it is not clear how *O’Shea* illuminated or was useful to the *Ponzi* decision. The *Ponzi* court’s reliance on these Supreme Court cases for the proposition that named plaintiffs must reside in the jurisdiction where their injury occurred is on shaky ground and overreaching. This Court refuses to follow *Ponzi*, which unravels defendants’ argument.

Even more damaging to defendants’ reliance on *Ponzi* is that the *Ponzi* Court based its holding on *Semeran v. BlackBerry Corp.*, No. 15-cv-750, 2016 WL 3647966, at 6 (D.N.J. 6 July 2016), which itself has now been overruled by the very judge in the District of New Jersey who

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<sup>2</sup> In fact, the *Ponzi* Court cited *Daimler* at an incorrect page number, that is, to a page where only facts were recited, and not where *Daimler* discussed the possibility of unnamed plaintiffs.

Importantly, *Daimler* could not concern named plaintiffs who had been injured where they did not reside. This is because *Daimler* concerned only taxpayers who paid Ohio state tax regardless of their residence. Such taxpaying to Ohio state treasury constituted in and of itself an attribute that created a closed and defined class. In other words, no payer of taxes to the Ohio state treasury could belong outside the class OR to an “out-of-state” class.

originally penned it.<sup>3</sup> Since *Back2Health Chiropractic Center, LLC v. Sentinel Insurance Company, Ltd.*, Civ. No. No. 20-6717 (JMV-MF), 2021 WL 960875, at \*6-\*7 (DNJ, 15 Mar 2021) explicitly backtracks from *Semeran*, this Court finds it fitting to upgrade its ruling in the MTD Opinion 2 on the traceability requirement of named plaintiffs at the motion to dismiss stage.

*Back2Health* involved a putative class action in which defendant insurance company was alleged to have breached plaintiff's insurance policy by failing to cover plaintiff's losses owing to halted business operations stemming from the Covid-19 pandemic. Defendant moved to dismiss plaintiff's nationwide class action claims for, among other things, lack of standing. In deciding this issue, the *Back2Health* Court relied unerringly on Third Circuit jurisprudence. It situated its holding squarely on the seminal case, *Neale v. Volvo Cars of N. Am.*, 794 F.3d 353, 362 (3d Cir. 2015), and on the sequential case, *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018). The *Back2Health* Court took the *Neale* holding and applied it directly to named class members. *Back2Health Chiropractic Center*, 2021 WL 960875, at \*6-\*7. See the *Neale* holding marked by \*\*\* below. Specifically, the *Back2Health* Court found that in a class action that was itself still uncertified there can be no distinction between putative class members and named class members. The *Back2Health* Court stated:

"The Third Circuit has established: \*\*\* "putative class members need not establish Article III standing. Instead, the 'cases or controversies' requirement is satisfied so long as a class representative has standing, whether in the context of

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<sup>3</sup> To wit, the *Ponzi* court stated:

"the Court finds that Plaintiffs' lack standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury. See *Semeran v. Blackberry Corp.*, No. CV 15-750, 2016 WL 3647966, at \*6 (D.N.J. July 6, 2016) (stating that '[a] named plaintiff must be a part of the class which he seeks to represent' and deciding standing issues at the pleadings stage 'in light of the fact that [p]laintiff was not a member of the Multi-State Class, and because such a class would require the court to apply the substantive law from numerous other states.') [citations omitted]". *Ponzi*, 447 F. Supp. at 223.

a settlement or litigation class." *Mielo v. Steak 'N Shake Operations, Inc.*, 897 F.3d 467, 478 (3d Cir. 2018) (quoting *Neale*, 794 F.3d at 362). \*\*\* [\*\*\* indicates the *Neale* holding].

**Both *Mielo* and *Neale* lend support to Plaintiff's position – that as long as the named plaintiff has standing, it can bring claims on behalf of a nationwide class. [emphasis added]." *Back2Health Chiropractic Center*, 2021 WL 960875, at \*6.<sup>4</sup>**

The *Back2Health* Court enunciated the basis for its holding:

"Article III standing is a constitutional requirement that directly impacts a court's subject-matter jurisdiction. As the Third Circuit in *Neale* recognized, it began with the Article III issue because a court has an obligation to assure itself of a party's standing. *Neale*, 794 F.3d at 358 (citations omitted). **As a result, the Court concludes that if the Third Circuit had concerns about a named plaintiff's standing to raise claims for putative out-of-state members, the Circuit would have addressed the issue *sua sponte*. The Third Circuit did not do so in either *Neale* or *Mielo*.** [emphasis added].

Here, Defendant cites to decisions from the District of New Jersey – including this Court's decision in *Semeran v. BlackBerry Corp.*, No. 15-750, 2016 WL 3647966 (D.N.J. July 6, 2016) – which found that a named plaintiff lacked standing to assert claims under the laws of states in which he did not reside. Def. Br. at 4. In *Semeran*, the parties did not raise *Neale*, and *Mielo* had not yet been decided. **In addition, the Court did not analyze *Neale* in *Semeran*. In any event, to the extent *Semeran* is inconsistent with *Neale* or *Mielo*, the Third Circuit's binding precedent controls.** As a result, Defendant's motion to dismiss for lack of standing is denied." *Back2Health Chiropractic Center*, 2021 WL 960875, at \*6-\*7. [emphasis added].

<sup>4</sup> The *Back2Health* Court went on to outline the facts in both *Neale* and *Mielo*:

"In *Neale*, eight named plaintiffs from six different states sought to represent a nationwide class of plaintiffs – or, in the alternative, six statewide subclasses from each of the states that a named Plaintiff was from – to bring design defect claims against Volvo. *Neale*, 794 F.3d at 356. Volvo argued that all putative class members must have Article III standing, but the Third Circuit rejected this argument and held that only the named Plaintiff must have standing.<sup>7</sup> [Footnote omitted herein] *Id.* at 358, 362. The *Neale* court characterized Volvo's arguments "related to the differences between claims among the separate statewide classes" as confusing Rule 23's requirements with Article III standing and noted that "whether [a class representative] may be allowed to present claims on behalf of others who have similar, but not identical, interests depends not on standing, but on an assessment of typicality and adequacy of representation." *Id.* at 368 (alteration in original) (quoting 7AA Charles A. Wright et al., *FED. PRAC. & PROC. CIV.* § 1785.1 (3d ed. 2014)). The Circuit rejected Volvo's challenge to the plaintiffs' standing but **remanded the case for different reasons**. *Id.* at 369. [emphasis added]. Thus, the Third Circuit would have permitted the named plaintiffs to proceed with the nationwide claims, indicating that the plaintiffs from six states had standing to assert claims on behalf of unnamed plaintiffs in the other forty-four states.

<sup>7</sup> Similarly, in *Mielo*, two plaintiffs who were directly injured at two Steak 'n Shake restaurant locations in Pennsylvania sought to sue on behalf of a class of people that may have been injured at Steak 'n Shake locations around the country. 897 F.3d at 473. Specifically, the named plaintiffs sought to enjoin Steak 'n Shake to adopt policies in compliance with the Americans with Disabilities Act. *Id.* at 474. Defendant Steak 'n Shake challenged the named plaintiffs' standing to seek relief beyond the two Pennsylvania locations at which they were directly injured. *Id.* at 480. The Third Circuit rejected the defendant's argument and noted that it conflated standing with the requirements of Rule 23. *Id.* The court determined that the named plaintiffs sufficiently alleged the elements of Article III standing, while concluding that they failed to satisfy the requirements of Rule 23(a). *Id.* at 482. Thus, the Third Circuit found that two plaintiffs that were injured in Pennsylvania had standing to pursue claims on behalf of a nationwide class of plaintiffs that were injured in other states." *Back2Health Chiropractic Center*, 2021 WL 960875, at \*6-7.

Based on the more comprehensive reasoning in the *Back2Health* case, this Court holds that, as to the Standing of Named Plaintiffs in the Proposed Economic Loss Master Complaint and the Proposed Medical Monitoring Complaint, the Court **GRANTS** plaintiffs' motion (Doc. No. 1694), **DENIES** the MFRs' Motion (Doc. No. 1690), the Pharmacies' Motion (Doc. No. 1692), and the Wholesalers' Motion (Doc. No. 1695), and **AFFIRMS** the Report at Doc. No. 1614: 10-12 and SMO 46 at Doc. No. 1615: ¶12.

### 3.2 Wholesaler's and Pharmacies Negligence in all Three Master Complaints

SMO 46 (Doc. No. 1615, ¶9) denied plaintiffs leave to amend the Master Complaints to assert negligence claims against the Pharmacies and the Wholesalers. The Report at Doc. No. 1614: 34-37 based that denial on the Special Master's review of the Amended Complaints and the parties' cited case law. Particularly telling in the Report is the finding that the proposed Amended Master Complaints lack allegations that any Wholesaler or Pharmacy knew of the nitrosamine contamination and failed to take reasonable steps in response to such knowledge. Doc. No. 1614 at 35.

Thus, the negligence claims rely wholly upon the breach of the legal duty that defendants should have known the valsartan they sold was contaminated. In essence, plaintiffs allege that, since Wholesalers and Pharmacies should have known the quality of the valsartan they sold, these defendants had a duty to investigate the manufacturers' / suppliers' Good Manufacturing Practices ["GMP"] to ensure wholesomeness.<sup>5</sup>

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<sup>5</sup> For example, the PPIMC at ¶624 states:.. Wholesaler Defendants and Retail Pharmacy Defendants assumed and breached their duties to Plaintiffs by failing to conduct due diligence on their generic suppliers to ensure compliance with current Good Manufacturing Practices and the drug supply was not adulterated, misbranded, and/or contaminated. Retail Pharmacy Defendants breached their duties to Plaintiff by failing to exercise reasonable care when dispensing VCD and when creating labels and packaging for those same drugs for resale. Wholesaler Defendants breached their duty to Plaintiffs by failing to exercise reasonable care in their acquisition and re-sale of products.

In reviewing the facts *de novo*, the Court finds the amended Master Complaints set forth these boiled-down allegations: Wholesalers and Pharmacies acquired contaminated valsartan and thus breached a duty, which contains within it an *a priori* duty. To wit: the first duty is these defendants should have known that the valsartan they distributed was contaminated, which imposes an *a priori* duty to investigate the manufacturers' GMPs and thereby ensure their sold drugs are uncontaminated. The Court notes this "duty within a duty" allegation cannot withstand the light of economic reality into how products, including pharmaceuticals, are sold worldwide through distributors.

First, as a practical matter, compliance with such a duty to investigate would have required the following conduct: agents of the Pharmacies and Wholesalers observing at the manufacturing facilities the actual processing of the active pharmaceutical ingredient [API]; and/or, regular reports from the MFRs to the Wholesalers or Pharmacies, which detailed the GMPs of their valsartan API manufacturing processes. These activities are the purview of the U.S. Food and Drug Administration ["FDA"] that presumably regulates the integrity and purity of generic drugs manufactured abroad and imported within, and whose inspection mechanisms may, or not. have been insufficient as to the imported valsartan API.

Second, for products distributed by other than the manufacturer, indemnification agreements between the manufacturer and the distributor are commonplace. In these, the manufacturer typically warrants the distributor will be made whole for any liability and loss arising from a consumer's use of the product. Although the Court lacks specific knowledge of the indemnification agreements among the different groups of defendants here, such indemnification agreements would eliminate any perception by the Wholesalers and the

Pharmacies that they bear a duty to investigate directly the Good Manufacturing Practices of the Manufacturers. Thus, because of the indemnification agreements, the Wholesalers and the Pharmacies would not have known to investigate, which directly refutes plaintiffs' assertion of a "should have known" duty.

Thus, the Court finds no facts--neither behavior nor an atypical economic reality between Mfrs and the Wholesalers and Pharmacies--that support the existence of a duty borne by downstream defendants to investigate MFRs' GMPs to confirm the purity of the sold, generic valsartan drugs.

As for whether caselaw points to such a duty, the Report notes plaintiffs' briefs lack any pertinent citation to legal authority holding that a distributor's duty of care encompasses the testing of the integrity of the manufacturer's products. In addition, the Court has conducted its own extensive, legal research on the duty owed by Wholesalers and Pharmacies to investigate the quality of the drugs they sell and has found little that relates to the facts here. The case cited by Plaintiffs, *Fagan v. AmerisourceBergen Corp.*, 356 F.Supp.2d 198 (E.D. N.Y. 2004), the Court finds not even remotely on point. The *Fagan* Court found a duty existed to refrain from distributing "counterfeit" drugs.<sup>6</sup> That is not the situation here. Plaintiffs term the contaminated valsartan as "misbranded" or "mislabeled". Typically, the term "misbranded" refers to a "counterfeit" or incorrectly labeled drug. Plaintiffs' use of the term "misbranded" to describe contaminated valsartan extends the logical, linguistic, and semantic

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<sup>6</sup> The *Fagan* Court quoted: The FDCA and its corresponding regulations impose a duty upon ABC, as a distributor of prescription drugs, to, *inter alia*, refrain from introducing or delivering into interstate commerce, and from receiving, any misbranded, including counterfeit, drug. See, 21 U.S.C. § 331(a) and (c). The same conduct reasonably necessary to comply with that statute is the same as that which would protect the public, and plaintiff, from misbranded or counterfeit drug sales. Accordingly, as in the *September 11* case [*In re September 11 Litigation*, 280 F.Supp.2d 279 (S.D.N.Y.2003), ABC already had an existing duty to refrain from the trade of counterfeit or otherwise diverted drugs. *Fagan*, 356 F.Supp. 2d. at 210.

meaning of "counterfeit" beyond that which Wholesalers and Pharmacies could have been apprised of. Put simply, to call the drugs at issue here "counterfeit" or "mislabeled" when they did contain valsartan API, albeit contaminated, introduces a meaning and a duty to investigate that Wholesalers and Pharmacies would not have known of, except for plaintiffs' *post facto* re-definition of the term "mislabeled".

. Accordingly, as to the Negligence Claims against the Wholesaler Defendants and the Pharmacy Defendants, the Court **DENIES** plaintiffs' motion (Doc. No. 1694) and **AFFIRMS** the Report at Doc. No. 1614: 34-37 and SMO 46 at Doc. No. 1615: ¶9.

### 3.3 Pharmacies Implied Warranty in all Three Master Complaints

#### 3.3.1 Plaintiffs have adequately objected to the conflation of strict liability claims with breach of implied warranty claims

The Report at Doc. No. 1614:25 denied plaintiffs leave to amend the Master Complaints to assert breach of implied warranty claims against the Pharmacy Defendants under the laws of Alabama, Arizona, Arkansas, California, Connecticut, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

The denial was based on two points: an analysis of the cases cited in Exhibit B to the Pharmacy Defendants' Brief in Support of their Motion to Dismiss the Master Complaints (ECF No. 523-3, Exhibit B), and on Plaintiffs' failure to refute with specificity the accuracy of the case

law cited therein. ECF No. 775:23. The Report also specifically points out that plaintiffs did not dispute the original conclusion in MTD Opinion 3 as to the breach of implied warranty claims against the Pharmacies.

In their objection to the Report's denial of leave to assert breach of implied warranty claims against Pharmacies<sup>7</sup>, plaintiffs aver they had indeed disputed at least twice Pharmacies' citation of caselaw at Doc. No. 523-3, Exhibit B ["the Chart"], which purportedly reported on caselaw from states that limit such claims. In particular, plaintiffs point to their opposition (Doc. No. 577: 66-67) to Defendants' Motions to Dismiss the Complaints as well as to their Reply (Doc. No. 1382: 33-35)<sup>8</sup> accompanying their Motion to Amend. They also aver in their objection to the Report at Doc. No. 1694:6-9 that the Pharmacies have improperly conflated a legal claim of strict liability with an implied breach of warranty claim such that the two claims merge into one. This conflation, they argue, needs disentangling in order to resolve their objection to the Report's ruling on implied warranty claims.

Pharmacies, in their motion seeking adoption of the Report and SMO 46 as to the breach of implied warranty claims, put forth no supporting arguments, but simply request affirmation of the Report. Doc. No. 1692-1:4-5. In their opposition to plaintiffs' objection to the Report on implied warranty claims (Doc. No. 1780:8-10), Pharmacies focus on innocent

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<sup>7</sup> under the laws of 36 states, the District Of Columbia, and Puerto Rico.

<sup>8</sup> Plaintiffs' Reply at Doc. No. 1382: 33-35 states:

The Court should apply the same standard as it did when it ruled on the Retail Pharmacy Defendants' previous 12(b)(6) briefing. MTD Order No. 3, at 23: When examining the Retail Pharmacy Defendants' argument, the Court closely reviewed the cited cases in order to apply the "recommended liberality" to implied warranty claims. Id. The Court specifically looked for "any jurisdiction where the Pharmacies' assertions likely did not apply or where the law was as yet unclear" such as "any case that either relied on a strict liability-failure to warn theory." Id. In essence, the Court analyzed cases like White and Shaerrr for the express purpose of excluding those cases from its decision-making process. As was the case when the Retail Pharmacy Defendants brought their Motion to Dismiss, cases like White and Shaerrr, which do not address the availability of a cause of action for breach of implied warranty and are limited to discussion of failure to warn claims, are inapposite. Defendants failed to cite to any of Plaintiffs' proposed amendments that address the arguments the Court previously analyzed and rejected.

seller statutes and on certain case law that either cite such statutes or declare retail pharmacies provide health services and do not transact sales, which necessarily eliminates warranty claims. This is substantially the same argument Pharmacies put forth in their Motion to Dismiss arguments and which their case law Chart at Doc. No. 523-3, Exhibit B exemplifies. During the review of defendants' original Motion to Dismiss (Doc. No. 523), the Court took pains to review each case in Pharmacies' Chart at Doc. No. 523-3, Exhibit B, which allegedly demonstrates that a breach of implied warranty claim did not and could not lie against Pharmacies. Thus, Pharmacies' legal strategy here, as it was in their MTD brief at Doc. No. 523-3, is to raise innocent seller statutes and related case law as a defense to strict liability and breach of implied warranty claims.

In response to the parties' arguments, the Court has revisited plaintiffs' opposition at Doc. No. 577: 66-67 to Defendants' Motions to Dismiss as well as plaintiffs' Reply (Doc. No. 1382: 33-35) to their Motion to Amend. We see that plaintiffs had indeed registered their opposition in these submissions to the dismissal of implied warranty claims and raised arguments that Pharmacies have conflated strict liability and implied warranty claims. The Court has also looked further into the question of how strict liability claims are distinguished from implied breach of warranty claims in case law and finds that plaintiffs arguments have some merit.

### **3.3.2 Disentangling strict liability claims from breach of implied warranty claims**

The Restatements of Torts<sup>9</sup> offer guidance as to the separability of claims for strict liability from breach of implied warranty against pharmacies, when both claims arise from the

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<sup>9</sup> Recognizing that no section of the Restatement Second or Third is law until adopted specifically by the state legislature, the Court finds the Restatements nonetheless inform on accepted and considered reasoning in the legal community.

same facts. The Restatement (Second) of Torts§ 402A<sup>10</sup> (*A Special Liability of Seller of Product for Physical Harm to User or Consumer*) states:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
    - (a) the seller is engaged in the business of selling such a product, and
    - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
  - (2) The rule stated in Subsection (1) applies although
    - (a) the seller has exercised all possible care in the preparation and sale of his product, and
    - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.
- ...

*Comment f. Business of selling.* ... this Section applies to any person engaged in the business of selling products for use or consumption . . . [and] therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor...

*Comment g. Defective condition.* The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition **not contemplated by the ultimate consumer**, which will be unreasonably dangerous to him...The **defective condition may arise** not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or **from the way in which the product is prepared** or packed. [emphasis added].

*Comment m. "Warranty."* The liability stated in this Section does not rest upon negligence. It is strict liability...The basis of liability is purely one of tort.

A number of courts, seeking a theoretical basis for the liability, have resorted to a "warranty," ... **There is nothing in this Section which would prevent any court from treating the rule stated as a matter of "warranty" to the user or consumer. But if this is done, it should be recognized and understood that the "warranty" is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales.**

...

The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. . . In short, "warranty" must be given a new and different meaning if it is used in connection with this Section. **It is much simpler to regard the liability here stated as merely one of strict liability in tort.** [emphasis added].

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<sup>10</sup> Restatement (Second) of Torts § 402A (1965) October 2021 Update

Thus the Restatement (Second) in general guides state courts to consider a breach of implied warranty claim as a strict liability claim, not governed by the UCC, and lacking reference to a "seller". Moreover, the Restatement (Third) of Torts (Products Liability)<sup>11</sup>, Chapter 2, §6 (e) specifically addresses liability of pharmacies:

A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

- (1) at the time of sale or other distribution the drug or medical device **contains a manufacturing defect** as defined in § 2(a)<sup>12</sup>; or
- (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

*Comment h. Liability of retail seller of prescription drugs and medical devices for defective designs and defects due to inadequate instructions or warnings.* The rule governing most products imposes **liability on wholesalers and retailers for selling a defectively designed product**, or one without adequate instructions or warnings, even though they have exercised reasonable care in marketing the product. See § 1, *Comment e*, and § 2, *Comment o*. Courts have refused to apply this general rule to nonmanufacturing retail sellers of prescription drugs and medical devices and, instead, have adopted the rule stated in Subsection (e). [quoted above]

That rule [§6 (e) quoted above] **subjects retailers to liability only if the product contains a manufacturing defect or if the retailer fails to exercise reasonable care in connection with distribution** of the drug or medical device. [emphasis added].

While the Court appreciates that strict liability claims and implied breach of warranty claims are legally separate claims sounding in tort and not to be conflated, there appears a blurred distinction between them for personal injury, especially as noted in the Restatement (Second) of Torts. To better understand this blurred distinction, the Court conducted a search query across all states, which included the terms "pharmacy" and "breach of implied warranty" claim to see if and how states have recognized separate claims of strict liability and

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<sup>11</sup> Restatement (Third) of Torts: Prod. Liab. Chapter 2 § 6 (1998) Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices, March 2022 Update

<sup>12</sup> Restatement (Third) of Torts § 2(a) states: A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings ...

breach of implied warranty of merchantability for injury caused by a pharmacist's conduct. That is, the aim of the research was to appreciate the legal bases how these two claims that typically ride together on the same facts are separately pleaded. The Court found barely a handful of cases, but which were informative nonetheless, and a few of which are préciséd here.

#### **NEW YORK:**

In *Bichler v. Willing*, 58 A.D.2d 331, 332-334, 397 N.Y.S.2d 57, 58-59 (1977), plaintiffs argued that a retail druggist, even if filling a prescription with an unadulterated drug should be treated no differently than any other retailer, and should be held responsible for a breach of the implied warranty of merchantability if the drug later produced harmful side effects. Since such an issue of implied warranty had not been considered previously in New York, the First Department- Appellate Division relied on a Florida case, *McLeod v. W. S. Merrell Co.*, 174 So.2d 736 (Fla.1965) and a North Carolina case, *Batiste v. American Home Products Corp.*, 32 N.C. App. 1, 231 S.E.2d 269 (1977), in which both state courts ultimately observed the warranty claim depended on the prescribing physician's judgment, and not on the druggist's, as to whether the drug was inherently merchantable. Consequently, the *Bichler* court declared no cause of action existed under New York law for breach of any implied warranties against a pharmacy.

The Southern District of New York in *Winters v. Alza Corp.*, 690 F.Supp.2d 350 (S.D.N.Y. 2010) extended that holding: "[E]ven the plaintiff here acknowledges, a pharmacist does not have a duty to inspect or test a prescription drug for latent dangers. *Bichler v. Willing*, 58 A.D.2d 331, 333, 397 N.Y.S.2d 57 (1st Dept.1977)", which speaks to the absence of a pharmacies' duty to ensure merchantability of a prescribed drug.

#### **PENNSYLVANIA:**

In *Makripodis by Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 361 Pa. Super. 589523 A.2d 374 (1987), the appellant mother had taken Benedictin during pregnancy for her nausea. Her son was born with congenital disorders because of that ingestion and sued Merrell-Dow Pharmaceuticals and Rite Aid. Against Rite Aid, she alleged both breach of the implied warranty of merchantability because Benedictin was unsafe for its ordinary purpose, and strict liability because Benedictin was a defective product and unreasonably dangerous due to the absence of proper warnings concerning potential to cause birth defects. This was the first instance in Pennsylvania of this double allegation against a retailer pharmacy for selling a drug

that later caused injury.

Relying on the Restatement (Second) of Torts [the Restatement adopted into Pennsylvania law] *comment h* and on *McLeod v. W. S. Merrell Co.*, 174 So.2d 736 (Fla.1965) cited above, the Superior Court held a pharmacist dispensing a physician-prescribed drug warrants ONLY:

- (1) they compounded the prescribed drug with due care,
- (2) in the strength and quantity prescribed,
- (3) using proper compounding,
- (4) the drug is pure and unadulterated, and
- (5) the drug label accord with the directives of the prescription

The Court found that Rite Aid's conduct met the warranties stated above and affirmed the trial court's decision to dismiss the breach of implied warranty of merchantability. The Court found it unnecessary to determine whether a retail prescription druggist is the provider of a professional service or a retail merchant.

However, in a later case, the Court found that a buyer must allege, in an implied warranty claim, breach of merchantability because the buyer is **relying upon the judgment of the [pharmacist] seller to select suitable goods**. [emphasis added]"'. *Thomas v. Carter-Wallace Inc.*, No. 316 Civil 1994, 1994 WL 904463 at \*3 (Pa.Com.Pl. 1 September 1994).

*Thomas* underscores that pursuing a claim for breach of implied warranty of fitness for personal injury is not effective; a claim for implied warranty of merchantability is more encompassing. And, although the *Thomas* plaintiffs were precluded from pursuing a warranty of fitness claim, they could still have pleaded a breach of warranty of merchantability as well as strict liability which the *Thomas* court, in relying on the Pennsylvania Supreme Court in *Mason v. Western Pennsylvania Hospital*, 499 Pa. 484, 453 A.2d 974 (1981) appeared agreeable to.

Thus, the situation in Pennsylvania regarding pursuing separate strict liability and breach of implied warranty claims for personal injury seems more fluid than Plaintiffs' Chart (Doc. 523-3 Exhibit B) notes.

#### VIRGINIA:

In *Gressman v. Peoples Service Drug Stores, Inc.*, Nos. LL-692-4 AND LL-693-4, 1988 WL 619115, (Circuit Court of VA, City of Richmond, 9 February 1988), the plaintiff bought a prescription medicine from the pharmacy. The bottle's label indicated chlorpromazine, but the drug was actually chlorpropamide, which the plaintiff ingested for several days, and which caused her brain damage and rendered her semi-comatose. Plaintiff sued, alleging the same

act of improperly filling the prescription was *inter alia* negligence and breach of implied warranty of merchantability.

The Court relied on Virginia's Drug Control Act ["the Act"] (which regulates in Virginia the practice of pharmacy) at 54-524.2 (24) and (26a) to dismiss the breach of implied warranty claim against the pharmacist. It found the Act defines the conduct of pharmacist in filling prescriptions and selling them as "health care" and "personal health service" and not as a "sale" within the meaning of the Uniform Commercial Code. *Gressman*, 1988 WL 619115, at \*3 and \*8.

However, the Court declined to apply the Act's definitions to the Pharmacy (*Id.* at \*4) relying instead on the Restatement (Second) of Agency § 217 (1958)<sup>13</sup>. Also, the Court found although the Act unambiguously defined a pharmacist as a "health care provider", it was conspicuously silent as to the definition of a pharmacy as a health care provider. The Court stated bluntly: "a retail pharmacy which buys drugs for resale to a consumer 'is not engaged in the service business.' [*Commonwealth v. Bluefield Sanitarium*, 216 Va. 686, 222 S.E. 2d 586 (1976)] *Id.* at 689."

Even though recognizing the Virginia Drug Control Act defined a pharmacist and pharmacy differently, the Court ultimately held that the Act's definition of a pharmacist's conduct must apply to the retail pharmacy:

"a sale of a prescription drug by a pharmacist is necessarily 'health care.' Accordingly, such a sale is part and parcel of the 'personal health service' which is the practice of pharmacy. See [the Act] 54-524.2(26a). As such, it is not a 'sale' within the meaning of the Uniform Commercial Code, and the court so holds." *Gressman*, 1988 WL 619115, at \*8.

Thus, the *Gressman* holding may appear more a policy statement than girded by well-founded law inasmuch as the *Gressman* Court never considered the Restatements of Torts, which views implied warranty as sounding in tort and not governed by the UCC.

These few cases show: some states may not allow a separate claim of breach of implied warranty against retail pharmacies under either version of the Restatement (Second) or (Third); some states may so allow under certain circumstances; and some state court decisions regarding these claims are not particularly well buttressed by statute or case law. In sum, the

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<sup>13</sup> Which states: "In an action against a principal based on the conduct of a servant in the course of employment."

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(b) The principal has no defense because of the fact that:

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(ii) the agent had an immunity from civil liability as to the act."

Court sees that the separability of strict liability claims from breach of implied warranty depends on individual state court interpretations of individual state laws and precedents and is clearly too variable to be restricted without convincing legal authority at this motion to dismiss stage of the proceedings.

In their Motion for Leave to Amend (Doc. 1382: 31-35), plaintiffs did raise the argument of separability of strict liability from implied warranty, but in a generalized way. Finding that plaintiffs had not directly opposed each case cited in Pharmacies' Chart (Doc. No. 523-3 Exhibit B), the Report denied plaintiffs' motion to raise implied warranty claims in those jurisdictions not directly opposed by plaintiffs. Nonetheless, the Report relied on plaintiffs' arguments against some specific cases as cited in Pharmacies' Chart and adjusted the listing states where plaintiffs could bring breach of implied warranty claims to include: Alaska, Colorado, Delaware, Idaho, Indiana, Montana, *Nebraska*, Nevada, *Oklahoma*, Oregon, Rhode Island, South Dakota, *Utah*, *Vermont* and *Wyoming*, with the Report's additions italicized and deletion struck out.

The Court confirms plaintiffs did not conduct a case-by-case, state-by-state opposition to the cases cited in Pharmacies' Chart: not in their Opposition to Defendants' Motion to Dismiss (Doc. 577: 66-67) or in Doc. 577-1:1-2 (Plaintiffs' Exhibit of case law), and not in their Motion for Leave to Amend (Doc. 1382:31-35), and not in their Objection to the Report (Doc. No. 1694: 6-9). Nonetheless, because of plaintiffs' more generalized argument in their Objection (Doc. No. 1694: 6-9) and fortified with a clearer view of the variability in state case law of the separability of strict liability and implied warranty claims, the Court re-examined the cases cited in Pharmacies' Chart (Doc. No. 523-3 Exhibit B). It found that not all state cases

cited in the Chart looked at whether a breach of implied warranty claim is separate from a claim for strict liability. Those states in the Chart with unclear case law on the relationship between a breach of implied warranty and strict liability are listed in the footnote.<sup>14</sup>

Because of its own research and *de novo* review of Restatements of Torts, the Court confirms plaintiffs generally did oppose Pharmacies' motion to dismiss by arguing Pharmacies' Chart conflated strict liability with breach of implied warranty. This confirmation is contrary to a finding in the Report and grounds the closer look given here to plaintiffs' argument. Because of its *de novo* review of the cases cited in the Chart, the Court also observes that some states

<sup>14</sup> **Connecticut:** The Chart cites: *Altieri v. CVS Pharm.*, No. Xo6CV020171626S, 2002 WL 31898323, at \*4-5 (Conn. Super. Ct. Dec. 13, 2002) for the proposition that no strict liability applies to pharmacies. Absent in this case is a claim for breach of implied warranty.

**District of Columbia:** *Ealy v. Richardson-Merrell, Inc.*, No. 83-3504, 1987 WL 159970, at \*3 (D.D.C. Jan. 12, 1987) DC Follows Restatement (Second) and as discussed above, this Restatement treats breach of implied warranty like strict liability. Ambiguous if breach of implied warranty claim allowed in D.C.

**Hawaii:** The Chart cites: *Birmingham v. Fodor's Travel Publ'n's, Inc.*, 833 P.2d 70, 79 (Haw. 1992) (travel guide is not a product); *Isham v. Padi Worldwide Corp.*, Nos. 06-00382, 06-00386, 2007 WL 2460776, at \*32 (D. Haw. Aug. 23, 2007) (scuba diving training program was a service so no strict liability or warranty claim). The implication is that these cases apply to pharmacies because pharmacies provide a service, not a product. But that implication is an assertion put forth by Pharmacies, unsupported by Hawaiian case law.

**Maryland:** The Chart cites: *Rite-Aid Corp. v. Levy-Gray*, 894 A.2d 563, 578 (Md. 2006) as case law that recognizes authority that limits pharmacy liability [for breach of implied warranty]. However, the Chart did not consider the earlier case, *Rite Aid Corp. v. Levy-Gray*, 162 Md. App. 673, at fn. 6 (2005) where the Court stated: "We need not decide in this case whether there can ever be an implied warranty of merchantability or of fitness for a particular purpose by a pharmacy dispensing a prescription drug..."; Pharmacies assert generally that pharmacies provide medical health care, but without a citation to Maryland state law authority.

**New Hampshire:** The Chart cites: *Siciliano v. Capitol City Shows, Inc.*, 475 A.2d 19, 25 (N.H. 1984); and, *Royer v. Catholic Med. Ctr.*, 741 A.2d 74, 76-77 (N.H. 1999). Pharmacies rely on the assertion that, as providers of a service, pharmacies are not subject to strict liability, in order to relate these cited cases to strict liability claims against Pharmacies. However, neither case concerns liability of a retail pharmacy nor a breach of implied warranty claim. And Pharmacies cite to no New Hampshire authority for support of the assertion that pharmacies provide a service.

**New Mexico:** The Chart cites: *Ruiz v. S. Pac. Transp. Co.*, 638 P.2d 406, 412 (N.M. Ct. App. 1981). This case is inapposite even to the strict liability issue. *Ruiz* concerns not a retail pharmacy, but a "non-user" of railroad equipment; there is no claim here for breach of implied warranty.

**Pennsylvania:** See the Court's discussion above.

**Puerto Rico:** The Chart cites: *In re Reinforced Earth Co.*, 889 F. Supp. 530, 534-35 (D.P.R. 1995). This case is inapposite even to a strict liability claim in that it concerns the opinion of a geologist about the structure of an earthen wall. There is nothing here about a pharmacy's liability or breach of implied warranty.

**Wisconsin:** The Chart cites: Wisconsin Statute 895.047-Product Liability , which states "If manufacturer can be shown strictly liable under the stated standards, then the seller may be held liable if certain other standards are met." The cited statute is not an innocent seller statute as Pharmacies aver and this statute does not address breach of implied warranty. Moreover, the plain language of the statute does not appear to limit the liability of a pharmacy corporation, if defined as retail seller.

do recognize a distinction between these claims and that some of the cases cited in Pharmacies' Chart are unclear, vague, or silent about a legal distinction between strict liability and breach of warranty claims against a retail pharmacy. The Court therefore finds plaintiffs' arguments regarding the separability of claims for breach of implied warranty carry some weight, the exact measure of which is unknown as plaintiffs have raised the issue but not detailed it.

Accordingly, and based on its revisiting of the caselaw in Pharmacies' Chart, the Court **REVISES** the ruling of the Report and **GRANTS** plaintiffs' motion to assert breach of implied warranty claims under the laws of: Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Indiana, Maryland, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Wisconsin, and Wyoming.

#### **4.0 CONCLUSION**

As to the Standing of Named Plaintiffs in the Proposed Economic Loss Master Complaint and the Proposed Medical Monitoring Complaint, the Court **GRANTS** plaintiffs' motion (Doc. No. 1694) and **DENIES** Manufacturer Defendants' ["MFRs"] Motion (Doc. No. 1690), Pharmacies' Motion (Doc. No. 1692), and Wholesalers' Motion (Doc. No. 1695), and **AFFIRMS** the Report at Doc. No. 1614: 10-12 and SMO 46 at Doc. No. 1615: ¶12;

As to the Negligence Claims against the Wholesalers and the Pharmacies, the Court **DENIES** plaintiffs' motion (Doc. No. 1694) and **AFFIRMS** the Report at Doc. No. 1614: 34-37 and SMO 46 at Doc. No. 1615: ¶9; and

As to the Breach of Implied Warranty Claims against the Pharmacies, the Court **REVISES** the ruling of the Report and SMO 46 at Doc. No. 1615: ¶6 and **GRANTS** plaintiffs' motion to assert breach of implied warranty claims under the laws of: Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Indiana, Maryland, Montana, Nebraska, Nevada, New Hampshire, New Mexico, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Wisconsin, and Wyoming.

Importantly, the Court notes that neither plaintiffs nor the Pharmacies have sought a separate decision of the breach of warranty claims for each Master Complaint. Nonetheless, the Court recognizes that breach of implied warranty claims for personal injury loss in the PPIMC and the PMMMC, if cognizable under the laws of a specific state, generally sound in tort and not under the UCC, thereby relieving any privity requirement between buyer and seller. The Court also notes that such warranty claims for economic loss in the PELMC may not sound in tort and may require a privity requirement. Nonetheless, the privity question for these claims has not been briefed and therefore not decided here. And, as the Court has already considered *de novo* the issue of implied warranty claims twice and as the Special Master has also considered this issue, the Court **DENIES** any further motions regarding the issues of separability of implied warranty claims from strict liability claims as well as any other "generalized" or specific refutations regarding implied warranty claims.

Further, the Court **AFFIRMS** in all other respects the Report (Doc. No. 1614) and SMO46, particularly, at Doc. No. 1615: paragraphs 1-5, 7-11.

Dated: 04 April 2022

s/ Robert B. Kugler

ROBERT B. KUGLER

United States District Court